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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,790	09/19/2001	Paul Laurence Cervi	13533-002001/F/USP81213	2047

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EXAMINER
SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/955,790	CERVI, PAUL LAURENCE	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claims 13, 14 and 24, the word "means" is preceded by the word(s) "stop" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

4. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

The use of "characterized in that" in Claim 1, should be changed to "wherein".

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 cites "instructions showing a method of use of the needle", but further in the claim cites a method of using the apparatus instead. Therefore the method in the preamble is not consistent with the claimed method.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 20 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim preamble states "instructions showing a method for the use of the needle", and instructions are considered to be printed matter, which is further considered to be nonstatutory. See In re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); Ex parte Gwinn, 112 USPQ 439 (Bd. App. 1955); and In re Jones, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6, 15, 16, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldridge.

Baldridge discloses a bone marrow biopsy instrument and method, and further discloses a handle; a tissue sampling means comprising a tube; the outer surface of the tube having an abrading formation extending in an axial direction; the abrading formation comprises a slot with at least one sharpened edge; the outer edges of the slot

are sharpened; the slot extends through the wall of the tube; a plurality of slots spaced circumferentially on the tube; the slot extends in an axial direction for at least 1 cm from the tip; the sampling tube bore extends through the handle; connection of a suction means to the sampling tube bore; the sampling tube has a sharpened, beveled tip; inserting the sampling tip into the bone to collect a sample in the bore; moving the sampling tip such that the bone is abraded to allow the sampling tip to be displaced sufficiently to weaken the connection between the sample and the bulk of the bone; and withdrawing the sampling tip with the sample therein. See Figures 9-12; Column 7, lines 22-68; and Column 8, lines 1-7.

9. Claims 22-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kedem.

Kedem discloses a hard tissue biopsy instrument with a rotary drive and further discloses a tissue sampling means with a sampling tube and a bore to receive a tissue sample; a handle connected to the sampling means for manual insertion of the needle; coupling means detachably connected to the tissue sampling means for coupling the needle to the rotary motor drive; the needle is adapted for both manual and motor driven insertion; the outer surface is in contact with the sampled tissue and the motor drive rotates at least the outer surface; a stop to inhibit over-insertion of the sampling tube into the sampled tissue; at least a portion of the stop is integrally formed with at least a portion of the handle; the coupling means is separable form the needle and comprises a shaft adapted to be received by a sampling tube, a connecting portion for connecting the motor drive and a drive portion to engage with the handle; a motor drive

and a protective sheath to enclose the motor drive except for a drive shaft; a shaft, and a connecting portion for connecting the motor drive and a drive portion to engage with the handle. See Column 4, lines 37-68; and Column 5, lines 1-44.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 13, 14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldridge as applied to claims 1 and 15 above, and further in view of Kedem.

Baldridge, as discussed above, discloses a bone marrow biopsy instrument, but fails to disclose a stop; and a motor drive for rotating the sampling tube.

Kedem, as discussed above, discloses a bone marrow biopsy instrument and further discloses a stop; and a motor drive for rotating the sampling tube. See Column 4, lines 37-68; Column 5, lines 1-44.

Since both Baldridge and Kedem disclose means for sampling bone marrow, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Baldridge to include the use of a stop and a motor, as per the teachings of Kedem, since it would provide a means of more effectively attaining the

bone marrow sample while preventing the tip of the sampling tube from being inserted too deep into the bone.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldridge in view of Kedem.

Baldridge, as discussed above, discloses a bone marrow biopsy instrument, with the use of a stylet, but fails to disclose the use of an electric drill to power thee sampling tube, and a sheath sized to fit around the drill. See Figures 9-12; and Column 7, lines 22-68; and Column 8, lines 1-7.

Kedem, as discussed above, discloses a bone marrow biopsy instrument and further discloses the use of an electric drill to power thee sampling tube, and a sheath sized to fit around the drill. See Column 4, lines 37-68; Column 5, lines 1-44.

Since both Baldridge and Kedem disclose means for sampling bone marrow, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Baldridge to include the use of a stop and a motor, as per the teachings of Kedem, since it would provide a means of more effectively attaining the bone marrow sample while preventing the tip of the sampling tube from being inserted too deep into the bone.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldridge as applied to claim 4 above, and further in view of Mittermeier et al.

Baldridge, as discussed above, discloses a bone marrow biopsy instrument but fails to disclose the slots in the abrading portion not extending to the end of the sampling tube.

Mittermeier et al disclose a bone marrow biopsy device and further disclose the slots in the abrading portion not extending to the end of the sampling tube. See Figure 9. Since both Baldridge and Mittermeier et al disclose bone marrow biopsy devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Baldridge to include a slot not extending to the distal end of the sampling tube, as per the teachings of Mittermeier et al, since it would provide a means of effectively penetrating the bone to remove the bone marrow.

Allowable Subject Matter

14. Claims 7-12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 102, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art pertains to bone marrow biopsy devices that also have slots or grooves at the distal end of the sampling tube, but do not disclose the use of a motor to drive the sampling tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

BS
February 14, 2003

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